

**Notice of Allowability**

Application No.

10/056,598

Examiner

Cynthia B. Wilder, Ph.D.

Applicant(s)

SORGE ET AL.

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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 1/8/2004.
2. ☒ The allowed claim(s) is/are 1-29 and 55-66.
3. ☒ The drawings filed on 24 January 2002 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
  6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
    - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
    - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),  
Paper No./Mail Date 1-12-04, 4-15-02
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),  
Paper No./Mail Date 3/4/2004
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

### EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ms. Kathleen Williams on March 4, 2004

The application has been amended as follows:

- (a) Non-elected claims 30-54 were canceled.

The following claims were added:

- 55. (New) A method of identifying the presence of a nucleotide at a predetermined position of a target polynucleotide, said method comprising:

- (a) incubating said target polynucleotide in a reaction mixture comprising an oligonucleotide primer comprising a first sequence which hybridizes to said target polynucleotide immediately 3' of said nucleotide and a second sequence which does not hybridize to said target polynucleotide in the presence of a third sequence, an oligonucleotide probe comprising said third sequence which hybridizes to said second sequence of said oligonucleotide primer, said oligonucleotide probe labeled with a first member of a pair of interactive labels, a polynucleotide chain terminator labeled with a second member of said pair of interactive labels, wherein said incubating permits said polynucleotide chain terminator to be incorporated into said

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oligonucleotide primer, and permits said oligonucleotide probe to hybridize to said oligonucleotide primer to permit said pair of interactive labels to generate a signal; and

(b) detecting said signal, wherein said detection is indicative of the presence of said nucleotide in said target polynucleotide. ---

- - 56. (New) A method of identifying the presence of a nucleotide at a predetermined position of a target polynucleotide, said method comprising the steps:

(a) incubating said target polynucleotide in a reaction mixture comprising an oligonucleotide primer comprising a first sequence which hybridizes to said target polynucleotide immediately 3' of said nucleotide and a second sequence which does not hybridize to said target polynucleotide in the presence of a third sequence, and a polynucleotide chain terminator labeled with a second member of a pair of interactive labels, wherein said incubating permits said polynucleotide chain terminator to be incorporated into said oligonucleotide primer;

(b) incubating the oligonucleotide primer comprising said second member of said pair of interactive labels with an oligonucleotide probe comprising said third sequence which hybridizes to said second sequence of said oligonucleotide primer and said probe labeled with a first member of said pair of interactive labels, such that formation of a hybrid between said oligonucleotide probe and said primer permits said pair of interactive labels to generate a signal; and

(c) detecting said signal, wherein said detection is indicative of the presence of said nucleotide in said target polynucleotide. - -

- - 57. (New) The method of claim 55 or 56, wherein said signal is generated by fluorescent resonance energy transfer. - -

- - 58. (New) The method of claim 55 or 56, wherein said oligonucleotide primer comprises a first sequence which hybridizes to said target polynucleotide and a second sequence which does not hybridize to said target polynucleotide in the presence of a third sequence. - -

- - 59. (New) The method of claim 58, wherein said oligonucleotide probe comprises said third sequence which hybridizes to said second sequence of said oligonucleotide primer. - -

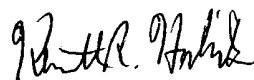
- - 60. (New) The method of claim 55 or 56, wherein said polynucleotide chain terminator is incorporated by a polynucleotide synthesis enzyme. \_ \_
- - 61. (New) The method of claim 55 or 56, wherein said reaction mixture further comprises one or more of a second, a third and/or a fourth polynucleotide chain terminator, wherein said first, second, third and fourth polynucleotide terminators are not identical. \_ \_
- - 62. (New) The method of claim 60, wherein said polynucleotide synthesis enzyme is a JDF-3 DNA polymerase. \_ \_
- - 63. (New) The method of claim 58, wherein said second sequence is at the 5' terminal of said first sequence. \_ \_
- - 64. (New) The method of claim 55 or 56, wherein said oligonucleotide primer comprises a separation moiety that permits separation of said oligonucleotide primer from said reaction mixture. \_ \_
- - 65. (New) The method of claim 64, wherein a target moiety is provided for said separation moiety to form a specific binding pair for separation. \_ \_
- - 66. (New) The method of claim 65, wherein said target moiety is attached to a solid support. \_ \_

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2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be emailed to [cynthia.wilder@uspto.gov](mailto:cynthia.wilder@uspto.gov). Since email communications may not be secure, it is suggested that information in such request be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (703) 308-1119. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
KENNETH R. HORLICK, PH.D.  
PRIMARY EXAMINER

3/8/04